Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
*Cardiovascular and Renal Drugs Advisory Committee*
*July 29, 2009*
Hilton Washington DC/Silver Spring, Maryland Ballroom
8727 Colesville Road, Silver Spring MD

# Draft Agenda

| | | |
|---|---|---|
| 8:00 a.m. | Call to Order<br>Introduction of Committee | Robert A. Harrington, M.D.<br>Chair, CRDAC |
| | Conflict of Interest Statement | Elaine Ferguson, M.S.<br>Designated Federal Official, CRDAC |

The committee will discuss supplemental new drug application (sNDA) 20–850/S–025, telmisartan tablets, 80 milligrams, Boehringer Ingelheim Pharmaceuticals, Inc., for the proposed indication of reduction in the risk of myocardial infarction, stroke, death from cardiovascular causes, or hospitalization for congestive heart failure in patients 55 years or older who are at high risk of developing major cardiovascular events.

| | | |
|---|---|---|
| 8:05 a.m. | FDA Opening Remarks | Norman Stockbridge, M.D.<br>Director, Cardiovascular and Renal Drug Products, CDER |
| 8:10 a.m. | Sponsor Presentations:<br>Introduction | Thor Voigt, MD. Senior VP of Medicine & DRA, Boehringer Ingelheim Pharmaceuticals, Inc. |
| | Clinical Need | James Young, MD.<br>Executive Dean, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University |
| | Principles Underlying the Analysis of Non-inferiority Trials | Janet Wittes, PhD.<br>Statistics Collaborative, Inc. |
| | Efficacy | Salim Yusuf, DPhil, FRCPC, FRSC.<br>Prof. of Medicine (McMaster University) and Director, PHRI, VP Research & CSO, Hamilton Health Sciences, Heart & Stroke Foundation Endowed Chair in CV Research |
| | Safety | Jeffrey Friedman, MD<br>Therapeutic Area Head Cardiovascular, Boehringer Ingelheim Pharmaceuticals, Inc. |
| | Risk / Benefit and Conclusions | James Young, MD. Executive Dean, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University |
| 9:40 a.m. | Questions to the Sponsor | |

Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
*Cardiovascular and Renal Drugs Advisory Committee*
*July 29, 2009*
Hilton Washington DC/Silver Spring, Maryland Ballroom
8727 Colesville Road, Silver Spring MD

# Draft Agenda

---

| | | |
|---|---|---|
| 10:10 a.m. | Break | |
| 10:25 a.m. | Clinical and Statistical Review of NDA 20-850/S-025 (Micardis) | Khin Maung U, M.D.<br>Clinical Reviewer, Division of Cardiovascular and Renal Products, FDA<br><br>Jialu Zhang, Ph.D.<br>Statistical Reviewer, Division of Biometrics I, FDA |
| 10:55 a.m. | Questions to the presenters | |
| Noon | Lunch | |
| 1:00 p.m. | Open Public Hearing | |
| 2:00 p.m. | Discussion of questions to committee | |
| 3:30 p.m. | Break | |
| 3:45 p.m. | Discussion of questions to committee (continued) | |
| 5:00 p.m. | Adjourn | |